10. 510(K) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The Assigned 510(k) number is _k050540

Submitter:

UCP Biosciences, Inc
1445 Koll Circle, Ste 111
San Jose, CA 95014
Tel: 408-392-0064
Fax: 408-392-0163

Date:

February 28, 2005

Contact Person:

Dr. Nancy Chen

Trade Name:

UCP Rapid™ Drug Screening Test Strips
UCP Rapid™ Drug Screening Test Devices

Common Name:

Amphetamine Test System
Barbiturate Test System
Benzodiazepine Test System
Cocaine and Cocaine Metabolite Test System
Methamphetamine Test System (Methamphetamine)
Methamphetamine Test System (MDMA)
Opiate Test System (Opiates)
Methadone Test System
Opiate Test System (Oxycodone)
Phencyclidine Test System
Cannabinoid Test System

Product Code:

DKZ (Amphetamine Test System)
DIS (Barbiturate Test System)
JXM (Benzodiazepine Test System)
DIO (Cocaine Test System)
DJC (Methamphetamine Test System)
DJC (Methamphetamine Test System--MDMA)

DMB (Methadone Test System)
DJG (Opiates Test System)
DJG (Opiates Test System--Oxycodone)
LCM (Amphetamine Test System—Phencyclidine)
LDJ (Cannabinoid Test System)

Regulation Section:

21 CFR 862§ 3100
21 CFR 862 § 3150
21 CFR 862 § 3170
21 CFR 862 § 3250
21 CFR 862 § 3610
21 CFR 862 § 3610 (MDMA)
21 CFR 862 § 3620
21 CFR 862 § 3250
21 CFR 862 § 3250 (Oxycodone)
21CFR 862 § 3100 (Phencyclidine)
21 CFR 862 § 3870

Panel: Toxicology (91)

Device Classification: II

Substantially Equivalent Devices:

Product: ACON One Step Drugs of Abuse Tests
Manufactured by ACON Laboratories

Product Description:
UCP Rapid™ Drug Screening Tests are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of drugs and their metabolites at the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Intended Use:
UCP Rapid ™ Drug Screening Tests are rapid, qualitative, competitive binding immunoassays and intended for qualitatively the detection of Amphetamine, Barbiturate, Cocaine, Methamphetamine, MDMA, Opiates, Methadone, Oxycodone, Phencyclidine, Marijuana (THC) and their metabolites in human urine at the following cut-off concentrations:

Amphetamine	1000 ng/mL
Barbiturates	300 ng/mL
Benzodiazepine	300 ng/mL

Cocaine	300 ng/mL
Methamphetamine	1000 ng/mL
Methadone	300 ng/mL
MDMA	500 ng/mL
Opiates300	300 ng/mL
Opiates 2000	2000 ng/mL
Oxycodone	100 ng/mL
Phencyclidine	25 ng/mL
Cannabinoids	50 ng/mL

The tests provide only preliminary test results, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drugs levels.

Comparison to Predicate Devices:

When compared to the predicates, UCP Rapid™ Drug Screening Tests provide the qualitative determination of the same twelve drugs in the same matrix, and utilizes the same cutoff concentrations. Both tests are immunochromatographic, lateral flow assays for the qualitative detection of drugs with visual, qualitative end results. Both tests are intended to provide preliminary analytical test results.

Safety and Effectiveness Data:

Accuracy

A clinical comparison study was conducted using 128 clinical specimens per each drug type including approximately 10% of the specimens containing one type drug at concentrations between -50% cutoff to cutoff ranges, another 10% of the specimens containing one type drug at concentrations between cutoffs to +50% cutoff ranges. The study was compared the test results between UCP Rapid™ Drug Screening Tests with ACON One Step Drugs of Abuse Tests. Total 64 positive clinical urine specimens and 64 negative clinical urine specimens were tested against each drug. All test results were confirmed with GC/MS analysis. UCP Rapid™ Drug Screening Tests demonstrated performance of > 96% for all drugs when performance was compared to a legally marketed device and GC/MS.

Other Information about Performance Characteristics:

The performance characteristics of UCP Rapid™ Drug Screening Tests was evaluated by precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study. The study results indicate that UCP

Rapid™ Drug Screening Tests perform satisfactorily when used according to the package inserts.

Conclusion:
UCP Rapid™ Drug Screening Tests is substantially equivalent to ACON Laboratories One Step Drug of Abuse Tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 9 2005

Dr. Nancy Chen
UCP Biosciences, Inc.
1445 Koll Circle, Suite 111
San Jose, CA 95112

Re: k050540
Trade/Device Name: UCP Rapid™ Drug Screening Test Strips
UCP Rapid™ Drug Screening Test Devices
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM
Dated: February 28, 2005
Received: March 2, 2005

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k050540
Device Name: UCP Rapid™ Drug Screening Test Strips
UCP Rapid™ Drug Screening Test Devices

Indications For Use:

The UCP Rapid™ Drug Screening Test Strips and UCP Rapid™ Drug Screening Test Devices are rapid, qualitative, competitive binding immunoassays for the detection of Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methamphetamine, MDMA, Opiates, Methadone, Oxycodone, Phencyclidine, Marijuana and their metabolites in human urine at the following cutoff levels:

Test	Calibrator	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepine	Oxazepam	300 ng/mL
Cocaine	Benzoylecgonine	300 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
Methadone	Methadone	300 ng/mL
MDMA	D, L-MDMA	500 ng/mL
Opiates 300	Morphine	300 ng/mL
Opiates 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Cannabinoids	11-nor-Δ^9-THC-9 COOH	50 ng/mL

The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

Prescription U x AND/OR Over-The-Counter Use ——
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k050540